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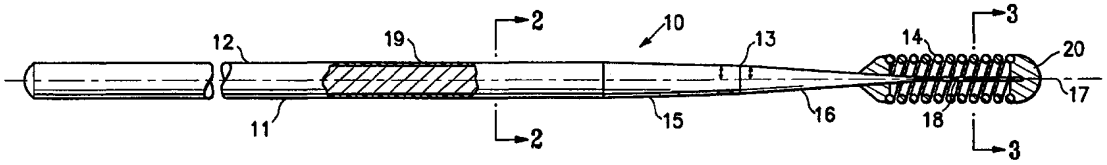

(57) Abstract

The invention is directed to a guidewire having a distal section with multiple distally tapered core segments with at least two contiguous distally tapering core segments in which the most distal tapered core segment preferably has a greater degree of taper than the proximally contiguous tapered core segment.

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STEERABLE GUIDEWIRE WITH ENHANCED DISTAL SUPPORT

BACKGROUND OF THE INVENTION

This invention relates to the field of guidewires for advancing intraluminal devices such as stent delivery catheters, balloon dilatation catheters, atherectomy catheters and the like within body lumens.

In a typical coronary procedure a guiding catheter having a preformed distal tip is percutaneously introduced into a patient's peripheral artery, e.g. femoral or brachial artery, by means of a conventional Seldinger technique and advanced therein until the distal tip of the guiding catheter is seated in the ostium of a desired coronary artery. There are two basic techniques for advancing a guidewire into the desired location within the patient's coronary anatomy, the first is a preload technique which is used primarily for over-the-wire (OTW) devices and the bare wire technique which is used primarily for rail type systems. With the preload technique, a guidewire is positioned within an inner lumen of an OTW device such as a dilatation catheter or stent delivery catheter with the distal tip of the guidewire just proximal to the distal tip of the catheter and then both are advanced through the guiding catheter to the distal end thereof. The guidewire is first advanced out of the distal end of the guiding catheter into the patient's coronary vasculature until the distal end of the guidewire crosses the arterial location where the interventional procedure is to be performed, e.g. a lesion to be dilated or a dilated region where a stent is to be deployed. The catheter, which is slidably mounted onto the guidewire, is advanced out of the guiding catheter into the patient's coronary anatomy over the previously introduced guidewire until the operative portion of the intravascular device, e.g. the balloon of a dilatation or a stent delivery catheter, is properly positioned across the arterial location. Once the catheter is in position with the operative means located within the desired arterial location, the interventional procedure is performed. The catheter can then be removed from the patient over the guidewire. Usually, the guidewire is left in place for a period

of time after the procedure is completed to ensure reaccess to the arterial location is it is necessary. For example, in the event of arterial blockage due to dissected lining collapse, a rapid exchange type perfusion balloon catheter such as described and claimed in U.S. Patent 5,516,336 (McInnes et al), can be advanced over the in-place guidewire so that the balloon can be inflated to open up the arterial passageway and allow blood to perfuse through the distal section of the catheter to a distal location until the dissection is reattached to the arterial wall by natural healing.

With the bare wire technique, the guidewire is first advanced by itself through the guiding catheter until the distal tip of the guidewire extends beyond the arterial location where the procedure is to be performed. Then a rail type catheter, such as described in U.S. Patent No. 5,061,395 (Yock) and the previously discussed McInnes et al. which are incorporated herein by reference, is mounted onto the proximal portion of the guidewire which extends out of the proximal end of the guiding catheter which is outside of the patient. The catheter is advanced over the catheter, while the position of the guidewire is fixed, until the operative means on the rail type catheter is disposed within the arterial location where the procedure is to be performed. After the procedure the intravascular device may be withdrawn from the patient over the guidewire or the guidewire advanced further within the coronary anatomy for an additional procedure.

Conventional guidewires for angioplasty, stent delivery, atherectomy and other vascular procedures usually comprise an elongated core member with one or more tapered sections near the distal end thereof and a flexible body such as a helical coil or a tubular body of polymeric material disposed about the distal portion of the core member. A shapable member, which may be the distal extremity of the core member or a separate shaping ribbon which is secured to the distal extremity of the core member extends through the flexible body and is secured to the distal end of the flexible body by soldering, brazing or welding which forms a rounded distal tip. Torquing means are provided on the proximal

end of the core member to rotate, and thereby steer, the guidewire while it is being advanced through a patient's vascular system.

Further details of guidewires, and devices associated therewith for various interventional procedures can be found in U.S. Patent 4,748,986 (Morrison et al.); U.S. Patent 4,538,622 (Samson et al.): U.S. Patent 5,135,503 (Abrams); U.S. Patent 5,341,818 (Abrams et al.); and U.S. Patent 5,345,945 (Hodgson, et al.) which are hereby incorporated herein in their entirety by reference thereto.

For certain procedures, such as when delivering stents around challenging take-off, e.g. a shepherd's crook, tortuosities or severe angulation, substantially more support and/or vessel straightening is frequently needed from the guidewire than normal guidewires can provide. Guidewires have been commercially introduced for such procedures which provide improved distal support over conventional guidewires, but such guidewires are not very steerable and in some instances can damage vessel linings when advanced therethrough. What has been needed and heretofore unavailable is a guidewire which provides a high level of distal support with acceptable steerability and little risk of damage when advanced through a patient's vasculature. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

The present invention is directed to an improved guiding device providing enhanced distal support while having a flexible distal tip to provide acceptable steerability and little risk of damage to linings when advanced through a patient's body lumen such as veins and arteries.

The guiding member of the present invention has an elongated core member with proximal and distal core sections and a flexible tubular body such as a helical coil disposed about and secured to the distal section of the core member. The distal core section has a plurality of distally tapering contiguous core segments having tapers of up to 25° and lengths of up to 15 cm. As used herein the measurement of tapers is the angle of a line tangent to the surface of the segment with respect to the longitudinal axis of the core member. The first

tapered core segment, which typically has a circular transverse cross-section, preferably tapers from the diameter of the adjacent proximal core section to a diameter of about half to about three quarters of the diameter of the adjacent proximal core section. The second tapered core segment, which also has a circular transverse cross-section, tapers from the smallest diameter of the first tapered core segment to a diameter of not more than one-half the smallest diameter of the first tapered core segment.

One presently preferred embodiment includes a first core segment with a taper in the distal direction and a distally contiguous second core segment having a taper in the distal direction greater than the taper of the first core segment. The taper of the first or proximal segment generally ranges from about 1° to about 12°, preferably about 2° to about 10° and the taper of the second or distal core segment generally ranges from about 2° to about 15°, preferably about 4° to about 12°.

In another presently preferred embodiment, the second tapered core segment has a length greater than the first tapered core segment , with the distal segment generally ranging about 1 to about 12 cm, preferably about 2 to about 10 cm and the distal segment generally about 1 to about 8 cm, preferably about 2 to about 6 cm. The tapered core segments may have circular transverse cross-sections and straight exterior surfaces, e.g. frusto-conical shape. However, other shapes are contemplated, e.g. curved exterior surfaces. Indeed, the taper of the contiguous core segments may have a continuously changing taper over all or part of both core segments.

The flexible tubular body such as a helical coil is secured by its distal end to the distal tip of the distal core section or to the distal tip of a shaping ribbon secured to the distal core section in a conventional fashion. The helical coil may be secured by its distal end by soldering, brazing or welding to form a rounded distal tip to the guiding member as done with commercially available guidewire for procedures within a patient's coronary artery.

In one presently preferred embodiment of the invention, the guidewire has an elongated proximal core section having a length of about 65 to about 280 cm

and a circular transverse cross-section with a diameter of generally about 0.010 to about 0.035 inch (0.30-0.46 mm), typically about 0.012 to about 0.018 inch (0.30-0.46 mm) for coronary anatomy.

In one presently preferred embodiment of the invention, the second tapered core segment is preferably followed distally with a manually shapable flattened core segment of about 1 to 4 cm in length which preferably has essentially constant transverse dimensions, e.g. 0.001 by 0.003 inch (mm). A helical coil having transverse dimensions about the same as the proximal core section is secured by its distal end to the flattened distal tip of the core member, e.g. solder, and by its proximal end at an intermediate position on the second tapered segment so that the distal end of the second tapered segment resides within the interior of the coil. The coil may have a length of about 2 to about 40 cm or more, but typically will have a length of about 2 to about 10 cm in length.

The guidewire of the invention provides the enhanced distal and proximal support needed for stent deployment, advancement of atherectomy devices and the like and provides a smooth transition between the proximal core section and the flattened distal tip of the core member while exhibiting excellent steerability. These and other advantages of the invention will become more apparent from the following detailed description of the invention when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an elevational view partially in section of a guidewire embodying features of the invention.

Fig. 2 is a transverse cross-sectional view of the guidewire shown in Fig. 1 taken along the lines 2-2.

Fig. 3 is a transverse cross-sectional view of the guidewire shown in Fig. 1 taken along the lines 3-3.

Fig. 4 is an enlarged view of the distal portion of the guidewire shown in Fig. 1 which indicates the tapers of the distal core section.

Fig. 5 is a partial elevational view of the distal core section of an alternative embodiment of the invention which has a separate shaping ribbon extending from the distal extremity of the core member to the distal end of the coil.

DETAILED DESCRIPTION OF THE INVENTION

Figs 1-3 depict a guidewire 10 which is a presently preferred embodiment thereof which has a core member 11 with a proximal core section 12, a distal core section 13 and a helical coil 14. The distal core section 12 has a first tapered segment 15 and a second tapered core segment 16 which is distally contiguous to the first tapered core segment. The second tapered segment 16 tapers at a greater degree than the first tapered segment and this additional taper provides a much smoother transition when the distal portion of the guidewire 10 is advanced through a tortuous passageway. The degree of taper of the first tapered core segment 15, i.e. the angle between the longitudinal axis 17 and a line tangent to the first tapered core segment 15 is about 2° to about 10°, whereas the taper of the second tapered core segment 16, i.e. the angle between the longitudinal axis and the second tapered core segment is larger than the first angle and is about 5° to about 10° such as is shown in the enlarged view of the guidewire 10 in Fig. 4. While only two tapered core segments are shown in the drawings, any number of tapered core segments can be employed. Moreover, all of a multiple of tapered core segments need not have increasing degrees of tapers in distal direction. However, two or more contiguous tapered core segments over a length of about 5 to 15 cm should have distally increasing degrees of tapering.

Typically, the first tapered segment is about 3 cm in length and the second tapered segment is about 4 cm in length. In a presently preferred embodiment, the guidewire 10 has a proximal core section 12 of about 0.014 inch (0.36 mm) in diameter, the first tapered core segment has a diameter ranging from 0.014 inch down to about 0.008 inch (0.36-0.20 mm) and the second tapered core segment has a diameter ranging from about 0.008 to about

0.002 inch (0.20-0.05 mm). A flattened distal tip 18 extends from the distal end of the second tapered core segment 16 to the body of solder 20 which secures the distal tip 18 of the core member 11 to the distal end of the helical coil 14. A body of solder 21 secures the proximal end of the helical coil 14 to an intermediate location on the second tapered segment 16.

The core member 11 is coated with a lubricious coating 19 such as a fluoropolymer, e.g. TEFLON ® available from DuPont, which extends the length of the proximal core section 12. The distal section 13 is also provided a lubricous coating, not shown for purposes of clarity, such as a MICROGLIDE ™ coating used by the present assignee, Advanced Cardiovascular Systems, Inc. on many of its commercially available guidewires. Hydrophilic coating may also be employed.

The core member may be formed of stainless steel, NiTi alloys or combinations thereof such as described in U.S. Patent No. 5,341,818 (Abrams *et al*) which has been incorporated herein. Other materials such as the high strength alloys described in U.S. Patent Application No. 08/829,465 (Fariabi), filed on March 28, 1997, entitled HIGH STRENGTH MEMBER FOR INTRACORPOREAL USE which has also been incorporated herein by reference.

The helical coil 14 is formed of a suitable radiopaque material such as platinum or alloys thereof or formed of other material such as stainless steel and coated with a radiopaque material such as gold. The wire from which the coil is made generally has a transverse diameter of about 0.003 inch (0.05 mm). The overall length of the coil 14 is typically about 3 cm. Multiple turns of the distal portion of coil 14 may be expanded to provide additional flexibility.

In an alternative embodiment shown in Fig. 5, the flattened distal segment of the core member shown in Fig. 1 is replaced with a shaping ribbon 30 which is secured by its distal end to the distal end of the coil 14 and by its proximal end to the distal extremity of the core member 11.

While the specific embodiments described above are directed to tapered segments with constant tapers along their lengths, the taper need not be constant. For example, the tapers of contiguous core segments may be

gradually increasing in the distal direction, with the taper, i.e. a tangent line, crossing the junction between the two adjacent tapers being a continuous function.

Guidewires are generally about 90 to about 300 cm in length, and most commercially available guidewires for the coronary anatomy are 175 cm in length. Recently, however, longer guidewires, e.g. up to 190 cm in length, are being offered commercially by a variety of suppliers, including the present assignee.

Multiple tapers may be ground simultaneously or as separate operations. A centerless grinder with profile capabilities may be used to grind the tapers simultaneously. A manual centerless grinding may be employed to create separate tapers in separate operations. Tapers may also be formed by other means such as chemical means, e.g. etching, or laser means.

Unless otherwise described herein, conventional materials and manufacturing methods may be used to make the guiding members of the present invention. Additionally, various modifications may be made to the present invention without departing from the scope thereof.

WHAT IS CLAIMED IS:

1. An elongated guidewire comprising:

a) an elongated core member having proximal and distal core sections, with the distal core section having a first tapered core segment and a distally contiguous second tapered core segment, each of said core segments tapering distally at angles of up to 25°; and

b) a flexible body disposed about and secured to the distal core section.

2. The elongated guidewire of claim 1 wherein the second tapered core segment has a greater degree of taper than the first tapered core segment.

3. The elongated guidewire of claim 1 wherein the second tapered core segment tapers at about 2° to about 15°.

4. The elongated guidewire of claim 1 wherein the second tapered core segment tapers at about 4° to about 12°.

5. The elongated guidewire of claim 1 wherein the first tapered core segment tapers at about 1° to about 12°.

6. The elongated guidewire of claim 1 wherein the first tapered core segment tapers at about 1° to about 10°.

7. The elongated guidewire of claim 1 wherein each of the first and second tapered core segments extend a length of about 1 to about 15 cm.

8. The elongated guidewire of claim 1 wherein the second tapered core segment is longer than the first tapered core segment.

9. The elongated guidewire of claim 1 wherein the first tapered core segment is about 1 to about 8 cm in length.

10. The elongated guidewire of claim 1 wherein the first tapered core segment is about 2 to about 6 cm in length.

11. The elongated guidewire of claim 1 wherein the second tapered core segment is about 1 to about 12 cm in length.

12. The elongated guidewire of claim 1 wherein the second tapered core segment is about 2 to about 10 cm in length.

13. The elongated guidewire of claim 1 wherein the flexible body is a helical coil with proximal and distal ends.

14. The elongated guidewire of claim 13 wherein the distal end of the helical coil is secured to the distal end of the core member.

15. The elongated guidewire of claim 13 wherein the helical coil has a proximal end secured to an intermediate location on the second tapered core segment.

16. The elongated guidewire of claim 13 wherein a shaping ribbon having proximal and distal extremities is secured by its proximal extremity to the distal end of the core member and by its distal extremity to the distal end of the helical coil.

17. The elongated guiding member of claim 2 wherein the helical coil is about 1.5 to about 40 cm in length.

18. The elongated guide member of claim 1 wherein the first and second tapered core segments have truncated conical shapes.

19. An elongated guidewire which comprises:

a) an elongated core member having a proximal core section, a distal core section with at least two contiguous tapered segments, a tapered proximal segment and a tapered distal segment having a taper which is up to 25° greater than the taper of the tapered proximal segment and a flattened distal segment distal to the tapered distal segment; and

b) a helical coil having a distal end secured to a distal end of the flattened distal segment.

20. The guidewire of claim 19 wherein the helical coil has a proximal end secured to an intermediate location on the tapered distal segment.

21. The elongated guidewire of claim 19 wherein the tapered distal core segment tapers about 2° to about 15°.

22. The elongated guidewire of claim 19 wherein the tapered distal core segment tapers about 4° to about 12°.

23. The elongated guidewire of claim 19 wherein the tapered proximal core segment tapers about 1° to about 12°.

24. The elongated guidewire of claim 19 wherein the tapered proximal core segment tapers about 1° to about 10°.

25. An elongated guidewire which comprises:

a) an elongated core member having a proximal core section, a distal core section with at least two contiguous tapered segments, a tapered proximal segment and a tapered distal segment having a length greater than the length of the tapered proximal segment and a flattened distal segment distal to the tapered distal segment; and

b) a helical coil having a distal end secured to a distal end of the flattened distal segment.

26. The elongated guidewire of claim 25 wherein the tapered proximal core segment is about 1 to about 8 cm in length.

27. The elongated guidewire of claim 25 wherein the tapered proximal core segment is about 2 to about 6 cm in length.

28. The elongated guidewire of claim 25 wherein the tapered distal core segment is about 1 to about 12 cm in length.

29. The elongated guidewire of claim 25 wherein the tapered distal core segment is about 2 to about 10 cm in length.

30. An elongated guidewire which comprises:

a) an elongated core member having a proximal core section, a distal core section with at least two contiguous tapered segments, a proximal segment having a first taper and a distal segment having a second taper different than the first taper, with the taper of the proximal and distal segments being continuous and a flattened distal segment distal to the tapered distal segment; and

b) a helical coil having a distal end secured to a distal end of the flattened distal segment.

31. The elongated guidewire of claim 30 in which the taper of the distal segment being greater than the taper of the proximal segment.

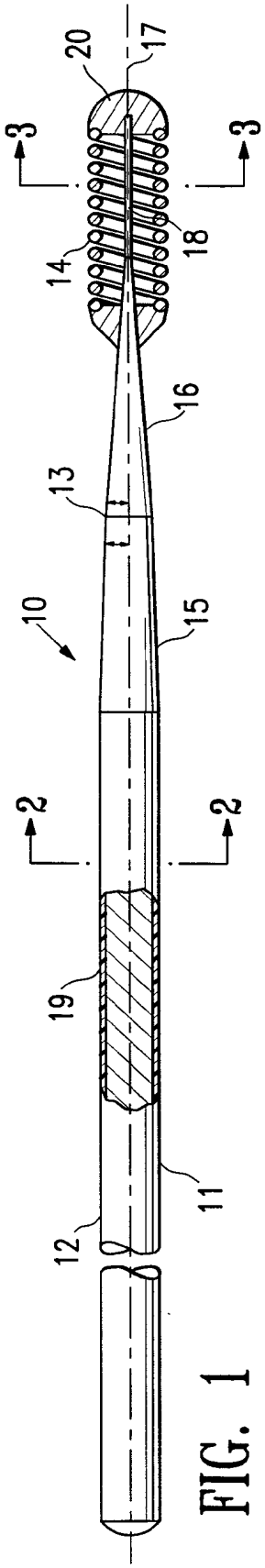

FIG. 1

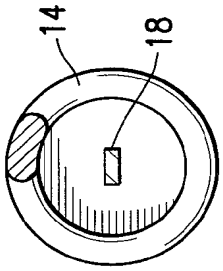

FIG. 3

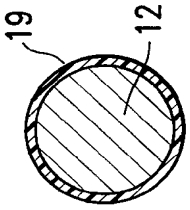

FIG. 2

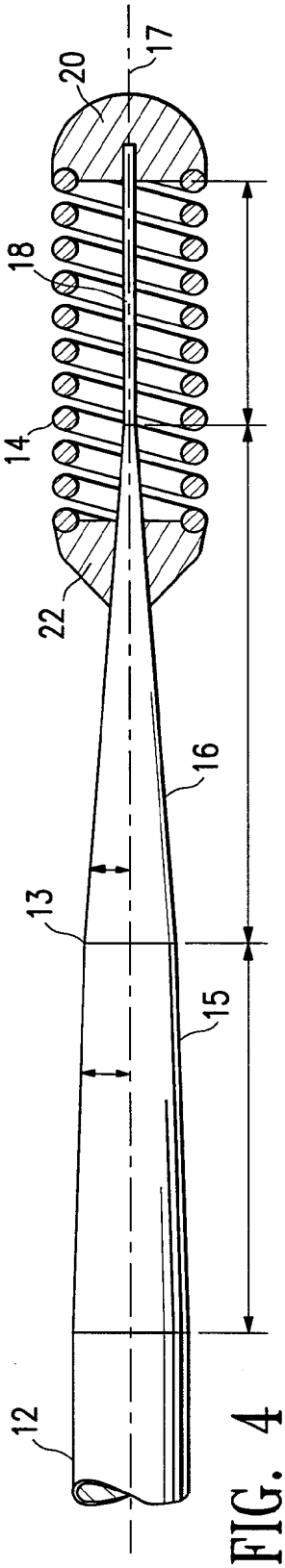

FIG. 4

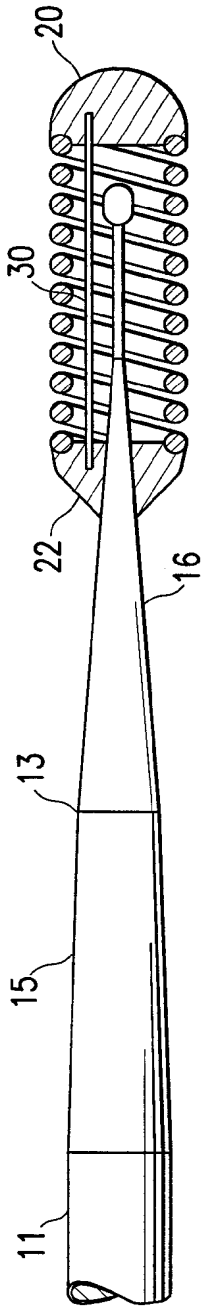

FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/11668

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X A	EP 0 744 186 A (TARGET THERAPEUTICS) 27 November 1996 see page 4, line 58 - page 5, line 34; figures 4,5	30 1,13,19, 25
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A	US 4 955 384 A (TAYLOR) 11 September 1990 see column 4, line 11 - line 45; figure 6	1,19,25, 30

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
18 August 1998	25/08/1998

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Kousouretas, I

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/11668

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

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